Applicant: Jyh-Lyh Juang et al. Attorney's Docket No.: 13217-002001

Serial No.: 10/050,665 Filed: January 16, 2002

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#### **REMARKS**

Claims 2, 15 and 24 are canceled without prejudice. Applicants reserve the right to pursue the canceled subject mater in one or more continuing applications.

Claims 1, 3-14, 16-23 and 25-28 have been amended. The amendments are supported throughout the application as filed, e.g., at page 2, lines 1-15. No new matter has been added.

Upon entry of this amendment, claims 1, 3-14, 16-23 and 25-28 will be pending and under examination.

## **Declaration**

The declaration is objected to because it does not identify the mailing address of each inventor. A revised declaration of Dung-Fang Lee, including Mr. Lee's mailing address, is being submitted under separate cover.

## Rejections under 35 U.S.C. § 102

I

Claims 1-8, 10, 14-22, 24-28 are rejected as anticipated by U.S. 5,004,687 to Miller (Miller). As presently amended, the claims recite a recombinant virus in which a first promoter is active in permissive host cells but inactive in non-permissive cells, and a second promoter that is active in non-permissive cells but inactive in permissive host cells. This rejection is respectfully traversed insofar as it may be applied to the present claims.

Miller discloses a recombinant virus (AcNPV-L1LC-galcat) that carries a polyhedrin promoter operably linked to an *E. coli* beta-galactosidase gene (beta-gal), and an RSV-LTR promoter fused upstream of the CAT gene. In permissive host cells (Sf21 cells), expression of the polyhedrin/beta-galactosidase fusion gene was detected 12 hrs post-infection (p.i.), and expression of the CAT gene was detected within 2 hours p.i. (Miller 6:3-22). CAT activity was also detected when AcNPV-L1LC-galcat was used to infect non-permissive Drosophila cells (Miller 8:38-64). Therefore, Miller shows that the RSV-LTR promoter (which the Examiner presumably believes to be the equivalent of the "second promoter" of the claims) is active in both permissive host cells and non-permissive cells. In contrast, the instant claims recite a

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recombinant virus in which a first promoter is active in permissive cells but inactive in non-permissive cells, and a second promoter that is active in non-permissive cells but inactive in permissive host cells. This limitation, whose support can be found, e.g., at page 2, lines 9-11, of the specification, has been explicitly added to claims 1, 14 and 22. Accordingly, the present claims are novel over Miller.

II

Claims 1-5, 8-9, and 12-13 are rejected as anticipated by U.S. Patent No. 6,589,783 to Novy et al. (Novy). This rejection is respectfully traversed. Novy et al. describes a vector (pTriEx-1) with three promoters, wherein each promoter is operable in a different type of host cell (chicken beta actin, for expression in a vertebrate host cell; T7-lac, for expression in a prokaryotic host cell; and the baculovirus promoter p10, for expression in an insect cell). The pTriEx plasmid contains only one exogenous gene, which is under control of one of the three promoters, depending on the type of host cell. Novy et al. does not anticipate the instant application because Novy et al. does not describe a recombinant virus that contains a "first nucleic acid sequence . . . operably linked to a first promoter, . . . and a second nucleic acid sequence . . . operably linked to a second promoter . . . "(Claim 1 of the instant application). Accordingly, the claims are novel over Novy because Novy does not meet all the limitations of the present claims.

In view of the foregoing, Applicants respectfully request that the rejection be withdrawn.

#### Rejections under 35 U.S.C. § 112, First Paragraph

Claims 1, 8-9, 12-14 and 16-23 are rejected for lack of written description and enablement with regard to "any" recombinant viruses. All the claims have been amended to recite that the virus is a <u>baculovirus</u>, thereby obviating the rejection.

# Rejections Under 35 U.S.C. §112, First Paragraph

Claims 1-23 are rejected as indefinite. In particular, claim 1 is said to be indefinite in the use of the phrases "capable of infecting a non-permissive cell" and "promoter is active in a host cell." This rejection has been addressed by amending claims 1, 14 and 22 to delete the phrase

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"capable of infecting a non-permissive cell" as superfluous and to specify that the host cell is a <u>permissive</u> host cell.

Claim 13 is said to be vague due to the use of acronyms. Claim 13 has been amended to spell out these art-recognized abbreviations.

Claim 14 is said to be vague due to lack of antecedent basis for the term "the recombinant baculovirus." Claim 14 has been amended to provide proper antecedent basis for this term.

Claim 22 is said to be vague in the recitation of the term "amplifying the virus."

Applicants submit that it would be perfectly clear to one skilled in the art that the term "amplifying" in this context means growing the baculovirus, rather than amplifying by PCR.

Nonetheless, in the interest of expediting prosecution, claim 22 has been amended to explicitly specify that "amplifying" the baculovirus is accomplished by growing the baculovirus.

In view of the foregoing, Applicants respectfully request that the rejection be withdrawn.

Applicants submit that all the pending claims are in condition for allowance. Enclosed is a Petition for Extension of Time along with the required fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: 30 March 200

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